

### **REMARKS**

In this paper, claims 16, 20 and 21 are amended, claims 1-15 and 17 are canceled, and new claims 22-33 are added. Claims 16 and 18-33 are pending. Reconsideration of this application, as amended, is requested.

Claim 16 has been amended to include the recitation of the second aperture being a rectangular vent through the second substrate. Support for this can be found, for example, as vent hole 574 in FIG. 21C and the related description on page 53. Claim 16 has also been amended to better clarify the physical structure of the sensor strip, by defining the relative lengths and widths of the first substrate and of the spacer layer. Support for these relative lengths and widths can be found, for example, in FIGS. 21A, 21B and 21C.

New dependent claim 22 is supported, for example, at page 2, line 26.

New dependent claim 23 is similar to original claim 6. New dependent claim 24 is similar to original claim 7. New dependent claims 25, 26 and 27 are similar to original claims 11, 12 and 13, respectively. New dependent claim 28 is similar to original claim 14.

New dependent claim 29 defines the relative lengths and widths of the second substrate and of the spacer layer. Support for these relative lengths and widths can be found, for example, in FIGS. 21A, 21B and 21C.

New dependent claim 30 is similar to original claim 15.

New dependent claim 31 defines the measurement period for the sensor strip. Support can be found, for example, on page 32, line 25.

New dependent claims 32 and 33 define the measurement period for the sensor strip based on the redox mediator. Support can be found, for example, on page 22, lines 10-11.

### **Claim Objections**

Claims 1 and 16 were objected to based on an informality. Claim 1 has been canceled, and claim 16 has been corrected. Withdrawal of this objection is requested.

### 103 Rejections of Claims 1-15

Claims 1-5, 8-11, 13 and 15 were rejected under 35 U.S.C. 103(a) as unpatentable over JP 9-159642 ("Ryohei I") in view of U.S. Patent No. 5,942,102 ("Hodges I") and WO 97/00441 ("Hodges II").

Claim 6 was rejected as unpatentable over Ryohei I in view of Hodges I and Hodges II and further in view of U.S. Patent No. 5,601,604 ("Maley").

Claim 7 was rejected as unpatentable over Ryohei I in view of Hodges I and Hodges II and further in view of U.S. Patent No. 5,650,062 ("Ikeda") and U.S. Patent No. 5,628,890 ("Carter").

Claim 12 was rejected as unpatentable over Ryohei I in view of Hodges I and Hodges II and further in view of U.S. Patent No. 5,437,999 ("Diebold") and U.S. Patent No. 5,723,345 ("Yamauchi").

Claims 1-5, 8-13 and 15 were rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,437,999 ("Diebold") in view of U.S. Patent No. 5,089,320 ("Straus"), U.S. Patent No. 5,095,407 ("Kanezawa"), "Enthone – Imaging Technologies Update ("Enthone"), Hodges I and Hodges II.

Claim 6 was rejected as unpatentable over Diebold in view of Straus, Kanezawa, Enthone, Hodges I and Hodges II and further in view of Maley.

Applicants disagree with each of these rejections. However, to facilitate prosecution and focus the claims more precisely to obtain desired coverage, claims 1-15 have been canceled, without prejudice, rendering all of these rejections moot.

### 103 Rejection of Claims 16-21

Claims 16-21 were rejected as unpatentable over Ryohei II in view of Hodges I and Hodges II and U.S. Patent No. 5,989,409 ("Kurnik"). Applicants respectfully disagree with the rejection and contend that amended claim 16 is patentable over the combination of Ryohei II in view of Hodges I and Hodges II and Kurnik.

Claim 16, the independent claim from which claims 17-21 ultimately depend, as amended, is directed to a sensor strip having:

a first substrate with at least one working electrode comprising gold thereon and at least one counter electrode comprising gold thereon, having a distance of 25-1000 micrometers therebetween;

a second substrate;

a spacer layer between the first and second substrates, the spacer layer having a length less than the length of the first substrate and a width the same as the width of the first substrate;

a first aperture along the proximal end of the sensor;

a second aperture forming a rectangular vent hole through the second substrate; and

a sample chamber extending from the first aperture to the second aperture, having a volume of no more than 1 microliter.

Ryohei II does not provide a spacer layer as required by amended claim 16, in that it has a length less than the length of the first substrate and a width the same as the width of the first substrate. Rather, the spacer layer of Ryohei II comprises two separate spacer pieces that together do not have a width the same as the width of the substrate. Neither Hodges I nor Hodges II remedies this deficiency in the spacer layer occupying the entire width of the substrate. Hodges I has a polyester core 4 (spacer), but as seen in FIGS. 10 and 11 of Hodges I, core 4 appears to only be present at the edges of the sensor, similar to that of Ryohei II. In Hodges II has no discussion regarding a core or spacer layer and from the figures, it is not apparent where any spacer layer may be located. Similarly, Kurnick has no discussion regarding a core or spacer layer and from the figures, it is not apparent where any spacer layer may be located. Kurnick also does not remedy the deficiency of the spacer layer as required by amended claim 16.

There are benefits in utilizing a spacer layer as required by claim 16, having a width that extends the width of the first substrate and a length the extends short of the first substrate, as compared to a two-piece spacer as disclosed by Ryohei II. Having a spacer as recited by claim 16 facilitates and improves the reproducibility of the sensor and particularly the sample chamber defined by the spacer layer by having an uninterrupted material that forms the boundaries of the sample chamber. Further, having a spacer as recited by claim 16 facilitates alignment of the

spacer to the edges of the substrate(s), improving the manufacturing process. One skilled in the art would not be lead to a larger spacer, having the dimensions recited by claim 16, at lest because it requires more spacer material than the two strip pieces of Ryohei II, and thus increases material cost for the sensor. Additionally, advanced processing or manufacturing technology is needed in order to remove a portion of the spacer layer to form the sample chamber, as compared to using two separate pieces. At least for this reason, one skilled in the art would not have used a spacer layer as required by pending claim 16, and at least for this reason, claim 16 and the claims that depend therefrom are patentable over the cited references.

Additionally, claim 16 is patentable over the cited references because none of the references, Ryohei II, Hodges I, Hodges II, nor Kurnick, provides a rectangular vent, which is the second aperture of the sample chamber. Ryohei II and Hodges II disclose circular vents, but do not lead one to rectangular vents.

At least for these reasons, Applicants contend that claim 16 is patentable over the combination of Ryohei II in view of Hodges I and Hodges II and Kurnik. Claims 17-21, and new claims 22-33, which ultimately depend from claim 16, are also patentable. Withdrawal of this rejection is requested.

## 102 Rejections

Claims 1-10 and 12-21 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,120,676 ("Heller").

Claims 1-15 and 17 have been canceled, rendering the rejection of claim 1-10, 12-15 and 17 moot.

Claim 16 has been amended to better define the claimed invention. Claims 18-21 depend therefrom. Applicants disagree that Heller anticipates claim 16, as amended.

For example, pending claim 16 requires that the sample chamber extends from a first aperture at the sensor strip end to a second aperture that is a rectangular vent through the second substrate. There is no disclosure in Heller of having a sample chamber extending to such a vent. Further, claim 16 requires that the sample chamber includes a recess having therein at least a portion of the working electrode and the redox mediator. There is no disclosure in Heller of having a recess in which a portion of the working electrode is present.

At least for these reasons, Heller does not anticipate claim 16 nor claims 18-21.  
Withdrawal of this rejection is requested.

Priority

Although Applicants do not agree with the Examiner's position that the subject matter of claims 2 and 17 (i.e., that the sample chamber recess is circular for embodiments where there is a second aperture), Applicants have canceled claims 2 and 17.

Information Disclosure Statement

Attached with this submission are the references requested by the Examiner: U.S. Patent No. 5,781,455 (Hyodo), EP 0 537 761, WO 91/09139, WO 98/35225, WO 98/43073, WO 98/58250, and the article by Vidal et al.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

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\_\_\_\_\_/Mara E. DeBoe/\_\_\_\_\_  
Mara E .DeBoe  
Reg. No. 40,066

